

## **REMARKS**

Claims 29-39, 41, 44, 46-52, and 59-63 are pending. Claims 40, 62, and 63 are allowed. Claims 29-39, 41, 46-52, and 59-63 are rejected. Claims 29, 44, 47, and 48 are amended.

Applicant respectfully requests correction of the Examiner's listing of the allowed claims. Because claim 40 was canceled and because the last sentence of "Allowable Subject Matter" regards claim 44; Applicant believes the Examiner meant claim 44, not claim 40, is allowed.

## **CLAIM INTERPRETATION**

Applicant respectfully disputes the interpretation that

..."a buffer at a concentration sufficient to maintain a pH in the range from about pH 3.6 to below pH 4.0" does not provide any specific requirements for the buffer". Therefore, any amount of buffer will function to maintain the pH in the desired range when the sample is already in the desired range. Consequently, this limitation does not necessarily impose any limitation on the claim other than the presence of a component with even minimal buffering capacity.

The buffer concentration is a bona fide limitation, at least because the claims encompass compositions of various pH values in which the buffer must maintain the pH from about 3.6 to below 4.0. A minimal concentration provides insufficient buffering capacity to maintain the desired pH range when the sample is already in the desired range (buffer: a solution selected or prepared to minimize changes in hydrogen ion concentration which would otherwise occur as a result of a chemical reaction." McGraw-Hill Dictionary of Chemical Terms, p. 62 attached (emphasis added); see also Applicant's January 17, 2007 Declaration, ¶¶13-14.

## **CLAIM REJECTIONS UNDER 35 U.S.C. §102**

Claims 29-39, 41, 46, 52, and 59-61 are rejected under 35 U.S.C. §102(b) as anticipated by Chen.

Applicant has amended claims 29-39, 41, 46, and 52 to define purified RNA as RNA that does not reveal the presence of DNA when assayed by reverse transcription polymerase chain reaction (RT-PCR). Support is at least at p. 5 lines 16-18 and ¶¶3-5 of Applicant's January 17, 2007 Declaration.

The rejection is improper with respect to claims 59-61, which recite a method that selectively precipitates higher molecular weight RNA from other RNA, as well as from DNA and protein. Chen does not disclose, nor would Chen's method inherently result, in selective precipitation of higher versus lower molecular weight RNA.

Thus, Applicant believes this rejection is overcome and respectfully requests its withdrawal.

## **CLAIM REJECTIONS UNDER 35 U.S.C. §103**

Claims 29-39, 41, 46, 52, and 59-61 are rejected under 35 U.S.C. §103(a) as obvious over Chen in view of Chomczynski '994.

Chen's requirement of a specific concentration range (0.005-0.02%) for his pH regulator (i.e., buffer) itself indicates that one skilled in the art would not be motivated to go outside this range. At concentrations above 0.02%, one skilled in the art would be concerned with potential detrimental

effects to the composition from the concentration of ions. At concentrations lower than 0.005%, one skilled in the art would be concerned with too few ions and insufficient pH regulation. Thus, one skilled in the art would not be motivated to combine Chen with Chomczynski, because Chen discloses the concentration he requires, while Chomczynski discloses "an amount sufficient to maintain the pH of the solution". Chen's specific concentration range would teach one skilled in the art not to stray outside this range.

Claims 48-51 are rejected under 35 U.S.C. §103(a) as obvious over Chen in view of Focus. These claims are now amended to define purified RNA. Because Chen does not isolate purified RNA for the reasons explained above, Applicant disagrees that Chen teaches all the claim limitations except for sedimenting prior to adding the phase separation reagent. Even assuming this teaching, which Applicant disputes, Focus is not a proper secondary reference. In applying Focus, the Examiner admits that the reagent is "similar to Chen's except for the pH". Claim 48 recites a pH range from about pH 3.6 to about 5.5 as a material limitation. Thus, the secondary reference admittedly differs in a material element.

Thus, Applicant believes that these rejections are overcome and respectfully request their withdrawal.

#### **CLAIM REJECTIONS UNDER 35 U.S.C. §112**

Claims 47-51 are rejected under 35 U.S.C. §112 ¶1 as not described, containing new matter. Applicant has amended the claims to overcome the rejection, reciting "without performing phase separation" which is the express language at p. 11 line 19, as the Examiner noted.

Thus, Applicant believes that this rejection is overcome and respectfully request its withdrawal.

#### **CONCLUSION**

Applicant believes the application is in complete condition for allowance and that no fees are due. If fees are required, the Examiner is authorized to charge them to Deposit Account No. 23-3000.

The Examiner is invited to telephone Applicant's undersigned representative with questions.

Respectfully submitted,  
WOOD, HERRON & EVANS, L.L.P.

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